K060081

FEB 13 2006

BASIS™ Spinal System – Crosslink® Plates
Summary of Safety and Effectiveness
February 2006

I. **Company:** **Medtronic Sofamor Danek, Inc. USA**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

Contact: **Richard W. Treharne, PhD**
Senior Vice President Regulatory Affairs

II. **Proposed Proprietary Trade Name: BASIS™ Spinal System**

III. **Classification Name(s)/Product Code(s): 888.3050, 888.3060, 888.3070**
Classification Name: Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, Pedicle Screw Spinal System
Product Codes: KWQ, KWP, MNH, MNI

IV. Product Description

The BASIS™ Spinal System consists of a variety of shapes and sizes of hooks, screws, bolts, nuts, plates, and vertebral body spacers, as well as ancillary instrument sets. The BASIS™ implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

BASIS™ hooks are intended for posterior use only.

The BASIS™ Spinal System implant components are made from medical grade titanium alloy. No warranties express, or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MSD Catalog for further information about warranties and limitations of liability. **Never use stainless steel and titanium implant components in the same construct.**

BASIS™ Vertebral Body Spacers must be used with additional anterior and/or posterior spinal instrumentation to augment stability. Specifically, the BASIS™ Anterior Thoracolumbar Plate, the BASIS™ Multi-Axial Screws, or the BASIS™ Fixed Angle Screws must be used with the BASIS™ Vertebral Body Spacers.

To achieve best results, do not use any of the BASIS™ components with components from any other system or manufacturer unless specifically allowed to do so in this or another Medtronic Sofamor Danek document. As with all orthopedic implants, none of the BASIS™ components should ever be reused under any circumstances.

The purpose of this 510(k) submission is to add CROSSLINK® components to the Basis™ Spinal System.

K060054

V. Indications

The BASIS™ Spinal System is intended for posterior, non-cervical fixation for the following indications: Spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar, or anterior cervical system, BASIS components are intended for the following indications: (1) spinal stenosis, (2) spondylolisthesis, (3) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (4) fracture, (5) pseudarthrosis, (6) tumor resection, and/or (7) failed previous fusion.

When used as a vertebral body replacement, BASIS™ Vertebral Body Spacers are intended to be used in corpectomy procedures to aid in surgical correction and stabilization of the spine. The device is indicated for use in the thoracolumbar spine (T1-L5) to replace and restore height of a resected vertebral body or portion thereof, excised for the treatment of tumor or trauma (i.e., fracture). BASIS™ Vertebral Body Spacers must be used with supplemental fixation. Specifically, BASIS™ Vertebral Body Spacers are to be used with the Medtronic Sofamor Danek BASIS™ Anterior Thoracolumbar Plates, Multi-Axial Screws, or Fixed Angle Screws. Additionally, BASIS™ Vertebral Body Spacers are intended to be used with bone graft.

Nota Bene: The BASIS™ Vertebral Body Spacers are not intended for cervical or posterior surgical implantation. The BASIS™ Anterior Cervical Plates are intended for anterior cervical intervertebral body fusions only. The BASIS™ Anterior Thoracolumbar Plates are intended for screw fixation/attachment to the anterolateral intervertebral bodies only.

VI. Substantial Equivalence

Documentation was provided which demonstrated the BASIS™ Spinal System CROSSLINK® Components to be substantially equivalent to EQUATION™ Fixation System Components previously cleared in K013962.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2006

Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132

Re: K060081
Trade/Device Name: BASIS™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: KWP, KWQ, MNH, MNI
Dated: January 9, 2006
Received: January 10, 2006

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K060081

Device Name: BASIS™ Spinal System

Indications For Use

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Except for hooks, when used as an anterolateral thoracic/lumbar, or anterior cervical system, BASIS components are intended for the following indications: (1) spinal stenosis, (2) spondylolisthesis, (3) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (4) fracture, (5) pseudarthrosis, (6) tumor resection, and/or (7) failed previous fusion.

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Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060081